6905. Twendex-PB timed disintegrating capsules. (F.D.C. No. 46912. S. No. 4-034 T.)

QUANTITY: 400 100-capsule btls. at Baltimore, Md.

SHIPPED: 5-11-60, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Capsules No. 118 Allison Twendex-PB Each Timed Disintegration Capsule contains: Dextro-Amphetamine Sulfate 20 mg. Phenobarbital 1 Gr. Warning: * * * Average: * * * Allison Laboratories, Inc., Baltimore, Maryland Distributors."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 99.5 percent of the declared amount of dextro-amphetamine sulfate and 98 percent of the declared amount of phenobarbital.

LIBELED: 1-18-62, Dist. Md.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2-8-62. Default—destruction.

DRUG FOR VETERINARY USE

6906. Medicated turkey feed. (F.D.C. No. 46566. S. No. 3-017 T.)

QUANTITY: 90 100-lb. bags at Laurel, Del.

SHIPPED: 10-13-61, from Baltimore, Md., by Sherwood Feed Mills, Inc.

LABEL IN PART: (Tag) "Sherwood Feeds 21% Turkey Grower Guaranteed Analysis * * * Medicated Active Drug Ingredient Amprolium 0.0125% (rubber stamped on label) Ingredients * * * Manufactured By Sherwood Feed Mills, Inc. Baltimore, Md. * * * 100 Lbs. Net Weight."

LIBELED: 10-16-61, Dist. Del.

CHARGE: 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use; 502(f)(2)—the labeling failed to bear the required warning statements that medicated feed containing amprolium should not be fed to laying hens, and must be withdrawn 4 days prior to slaughtering the birds for food; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 1-31-62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

6907. Various antibiotic drugs. (F.D.C. No. 46963. S. Nos. 43-301/5 T.)

QUANTITY: 7,854 vials, packaged 10 vials to a box, of *procaine penicillin G in aqueous suspension;* 12,056 vials, packaged 10 vials to a box, 19,640 vials and 3,086 vials, of *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution;* and 10 ctns., each containing 10 vials of a commingled lot of *procaine penicillin G in aqueous suspension and procaine penicillin G in crystalline dihydrostreptomycin sulfate solution,* at Philadelphia, Pa.

SHIPPED: 8-1-61 and 8-14-61, from Des Moines, Iowa, and Mankato, Minn. These were return shipments.

RESULTS OF INVESTIGATION: Analysis showed that the *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* contained approximately (12,056-vial lot) 81 percent, (portion of 10-ctn. lot) 51 percent, and (19,640-vial lot) 82 percent of the declared amount of penicillin. The 7,854-vial lot of *procaine penicillin G in aqueous suspension* and the 19,640-vial lot and 3,086-vial lot of *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* bore labels containing expiration dates which had expired.

LIBELED: 2–8–62, E. Dist. Pa.

CHARGE: *Procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* (12,056-vial lot, 19,640-vial lot, and portion of 10-ctn. lot), 501(c)—when shipped and while held for sale, the strength of the article differed from that which it was represented to possess, namely, "Each 2 cc dose contains 400,000 units of crystalline procaine penicillin G."

502(l)—when shipped and while held for sale, the *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* (all lots) was composed in part of a kind of penicillin and of a streptomycin derivative, and the *procaine penicillin G in aqueous suspension* (all lots) was composed in part of a kind of penicillin, and such articles were not from batches with respect to which certificates or releases were in effect pursuant to 507 and the articles were not exempt from that requirement.

DISPOSITION: 4–18–62. Default—destruction.

6908. Various prescription drugs. (F.D.C. No. 46960. S. Nos. 54–861/72 T.)

QUANTITY: 2,671 tablets and capsules and 69½ pts. of liquid drugs at Jacksonville, Fla., in possession of Hermax Corp.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida and (some labels), the names and addresses of manufacturers, packers, or distributors outside the State of Florida.

LIBELED: 2–5–62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the statement "Professional Sample" or similar wording on the labels of a number of the articles was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—a number of the articles failed to bear labels containing the common or usual name of each active ingredient; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations; 502(l)—a number of the articles were drugs composed in whole or in part of a kind of penicillin, and were not from batches with respect to which certificates or releases were effective pursuant to 507 in that certification of the articles under their present labels had not been obtained; and 503(b)(4)—a number of the articles were subject to the provisions of 503(b)